

### **REMARKS**

The claims now extant for examination, 1-5, 8-14, 16-20 and 22-29. No prior art is cited against the claims.

The examiner is thanked for his recognition that he "claims are deemed free of the prior art...". Applicant's appreciate the thorough and thoughtful consideration given by the examiner in the examination of this application. However, for the reasons discussed below, applicants submit that the instant claims comply with both the first and second paragraphs of 35 USC 112.

A. The rejections of original claims 1 and 4-12 under 35 USC 112, ¶ 2

1. *The expression "and/or" with respect to the activities (¶ 4)<sup>1</sup>*

The expression is one long used in the English language and has a clear meaning as note Webster's New Collegiate Dictionary, copy appended hereto. The meaning in these claims is clear: the enzyme can have either one of the activities or both.

2. *The question of duplication involving parts b) and c) (¶ 5)*

Clearly part b) and part c) are not duplicates. Part b) is directed to variations of

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<sup>1</sup> The "¶" followed by a number indicates the paragraph number used by the examiner in the Office Action

the sequence according to the degeneracy of the genetic code that means according to the genetic code one amino acid can be encoded by more than one nucleic acid triplet. For example the triplets UCU, UCC, UCA and UCG encode the amino acid Serine. Part c) of claim 1 is directed to derivatives of the sequences having the enzymatic activity of a delta-6-acetylenase/desaturase independently from the degeneracy of the genetic code.

3. *The meaning of “negligible reduction in the enzymatic action”* (Examiner’s ¶ 6)

As is made clear in *In re Watson*, 517 F.2d 465, 186 USPQ 11, 20 (CCPA 1975), Claim language must be read in light of the application disclosure as it would be interpreted by one of ordinary skill in the art; as well as in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd.Pat.App. & Int. 1989):

In rejecting a claim under the second paragraph of 35 USC 112, it is incumbent on the examiner to establish that one of ordinary skill in the pertinent art, when reading the claims **in light of the supporting specification**, would not have been able to ascertain with a reasonable degree of precision and particularity the particular areas set out and circumscribed by the claims. [Emphasis added.]

Turning to applicant’s disclosure at page 8, lines 16-19, it is manifestly clear how the skilled worker would interpret the expression.

4. *The “unduly alternative” rejection of claim 6 and 7 (§ 7)*

Applicants’ are unaware of any legal authority for this rejection. However in the spirit of cooperation, applicants have broken down the three possibilities of claim 6 into separate new claims 24, 25 and 26. This mandated the breaking down of claim 7 into separate new claims 27, 28 and 29. This should overcome the “unduly alternative” rejection.

5. *The “unduly alternative” rejection of claim 8 (§ 8)*

The expression “or nonfunctional” has been deleted which should remedy the “unduly alternative” problem.

Applicants’ once again challenge the propriety of an “unduly alternative” rejection. Compare, for example, the situation of a Markush grouping which can include thousands (if not millions) of alternative compounds, which is perfectly acceptable.

6. *The meaning of “functional” and its antecedent basis in claim 8 (§ 9)*

Applicants’ specification is replete with the explanation and use of the term “functional”. See, inter alia, page 7, lines 5-9; page 8, lines 20-32; and page 9 lines 10-28 and 31-35.

Nor is it clear how the adjective “functional” lacks antecedent basis. If the rejection is continued the examiner is respectfully requested to explain why antecedent basis is necessary for this adjective and, if so, how the claim can possibly be modified to correct the alleged problem.

7. *The meaning of “oil-producing organism”*

The term “oil-producing organism” is not indefinite. The specification, which is written for the skilled worker teaches for example different oil-producing organisms on page 19 (lines 43-45) and page 20 (lines 1 and 22 to 29).

8. *Conclusion regarding § 112, second paragraph*

It is therefore submitted “that one of the ordinary skill in the pertinent art, when reading the claims in light of the supporting specification, would...have been able to ascertain with a reasonable degree of precision and particularity the particular areas set out and circumscribed by the claims.” *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd.Pat.App.&Int. 1989).

**B. The rejections of original claims 1-12 under 35 USC 112, first paragraph: the “written description” and “enablement” requirements (§§ 12 and 13)**

In support of his position the examiner cites *University of California v Eli*

*Lilly*, 43 USPQ2d 1398, 1406 [sic: 1405-1506]<sup>2</sup> (fed.Cir. 1997) (*Lilly*). However, *Lilly* is inapposite to the facts in this case. More in point, under the instant facts, is *In re Cavallito*, 282F.2d 363, 127 USPQ 206 (CCPA 1960) at 127 USPQ 206:

The appealed claim covers a very large number of chemical compounds which may be developed in the future and which will possess the structure which appellants assert and the Patent Office admits is a novel structure. Due to the nature of chemical compounds and chemical process it is conceivable that an almost infinite number of compounds may be developed by chemists if they have before them the teachings which appellants assert to be new in this field, namely, the particular structure and molecular arrangement of their new compounds. It seems to us that it is proper for the Patent Office to examine such assertions of patentability with great care but, when that has been done, the standards by which the ultimate determination of patentability or unpatentability should be made are those standards which Congress has provided in the patent statutes.

*Lilly*, unlike the facts in the instant application, held that “a cDNA is not defined or described by the mere name ‘cDNA.’” Indeed, on the same page of *Lilly* cited by the examiner, *consistent* with the instant facts, the court noted:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. This is analogous to enablement of a genus under § 112¶ 1, by showing of enablement of a representative number of species within the genus. See *Angstadt*, 537 F.2d at 502-03, 190 USPQ at 218 (deciding that applicants “are not required to disclose every species encompassed by their claims even in an unpredictable art” and that the disclosure of forty working examples sufficiently described subject matter of claims directed to a generic process); *In re Robins*, 429 F.2d 452, 456-57, 166 USPQ 552, 555 (CCPA

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<sup>2</sup> The examiner's quote is somewhat out of context

1970) ("Mention of representative compounds encompassed by generic claim language clearly is not required by § 112 or any other provision of the statute. But, where no explicit description of a generic invention is to be found in the specification ... mention of representative compounds may prove an implicit description upon which to base generic claim language.")

The examiner has failed to point out, as is his burden, why the written description does not "clearly allow persons of ordinary skill in the art to recognize that [applicants] invented what is claimed ." *In re Gosteli*, 872 F.2d 1008, 10 USPQ 2d 1614 (Fed.Cir. 1989).

The examiner states that undue experimentation would be required to make and use the invention as claimed. However the examiner has not sustained his burden of going forward to establish undue experimentation. Moreover, "[s]ome experimentation, even if complex, is permitted." *M.I.T.v.A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed.Cir. 1985). Applicants submit that applicants disclosure does not cross the threshold of "undue" experimentation.

Given the clear teachings in applicants' specification, it is manifest that applicants were in full possession of the invention and that the skilled worker, with applicants' disclosure before him/her, would have well understood how to "make and use" the invention.

There is enough guidance in the specification for the skilled worker to practice applicants' invention in all its different aspects. In addition to the expression of the genes in yeasts the skilled worker is guided how to transform different organisms such as microorganisms and plants on page 18 to 20. A lot of different useful vector are disclosed and different transformation protocols, which are in general used by the skilled worker. Examples 3, 4, 5 and 10 teach the creation of transformed plants. The extraction of the oils are disclosed in examples 9 and 11.

Furthermore applicants are not in agreement with the arguments raised by the examiner that the references clearly shows that it is not possible to predict the enzymatic activity of the inventive enzymes. The references of Doerks, Smith et al., Brenner and Borks are theoretical considerations without any experiments. It is not possible to predict the enzymatic function with a 100% certainty the error is in the range of at least 8% (see Brenner, first page, second column, second paragraph, second sentence). In applicants case a test system for the enzymatic function is disclosed in the specification (see example 9). With said system it is possible to identify the sequences covered by the claims. Therefore the skilled worker is able to practice the invention and there is no undue experimentation for him. The claims scope is not broader then the written description.

**C. Conclusion**

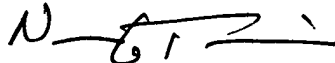
In view of the foregoing, allowance is respectfully solicited.

A check to cover the fee for one month extension of time is attached.

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees to Deposit Account No. 11-0345. Please credit any excess fees to such deposit account.

Respectfully submitted,

KEIL & WEINKAUF

A handwritten signature in black ink, appearing to read 'N. G. Torchin', with a stylized flourish at the end.

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